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EXAMINER

PREBILIC, PAUL B

ART UNIT PAPER NUMBER

3738

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/858,035

Applicant(s)

EDWIN ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-53 and 56 is/are rejected.
- 7) ☒ Claim(s) 54 and 55 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47 and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 47 and 48 lack original support where only overlapping polymer layers with no additional inner and outer tubular elements is originally disclosed; see page 14, line 28 to page 15, line 3 of the specification. Therefore, the claimed invention lacks original support because it is claiming a combination of species that was not originally disclosed. In other words, there is no support for the combination of overlapping polymer-clad layers encapsulated by inner and outer tubular substrates as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 47 and 48 and as an alternative to the Section 112, first paragraph rejection above, it may be that the combination of species has implicit

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support. If so, then the claims are indefinite because they lack clear antecedent support from the specification.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41, 42, and 44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,264,684. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are more detailed and narrower in scope than that of the present claims such that they are read on thereby. Therefore, the present claims are considered to be obvious over the patented claims under double patenting doctrine.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41, 42, 44, and 45 are rejected under 35 U.S.C. 102(e) as anticipated by Pinchuk et al (US 5,968,091) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pinchuk et al (US 5,968,091) alone. Pinchuk anticipates the claim language where the elongate support member as claimed is the wire stent (130) of Pinchuk; see Figure 7. In addition, the polymer cladding as claimed is met by the polycarbonate urethane coating of Pinchuk which overlaps at adjacent zigzags (34, 36) and are joined thereat; see column 5, lines 40-55 and column 2, line 55 to column 3, line 2.

Alternatively, the method steps in these claims pertaining to 'helically wrapping the cladded wire member into an open cylinder structure' constitute a different manner of making the same product as Pinchuk. The Examiner asserts that such claimed method steps result in a product that is at least substantially identical to the Pinchuk device; see MPEP 2113, which is incorporated herein by reference. Therefore, the Examiner asserts that the claimed device is at least clearly obvious over Pinchuk alone.

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With regard to claim 44, Applicant is directed to column 3, lines 21-52. Also, polycarbonate polyurethane is a type of polyurethane as claimed.

With regard to claim 45, ELIGLOY of Pinchuk is a shape memory alloy as claimed and tantalum is a type of biocompatible spring metal alloy as claimed; see Examples 9 and 12 of Pinchuk.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al (US 5,968,091) in view of Dotter (US 4,503,569). Pinchuk discloses materials that have a resilient or general shape memory property but fails to disclose a clear teaching a shape memory material with an austenitic state as claimed. However, Dotter teaches that it was known to use austenitic state shape memory materials in the art; see the abstract, the figures, and column 4, lines 25-40. Hence, it is the Examiner's position that it would have been obvious to use austenitic state shape memory materials in the Pinchuk invention so as to more precisely control the expansion of the stent and for the same reasons that Dotter uses the same.

Claims 47-53 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al (US 5,968,091) in view of Lee (US 5,123,917).

With regard to claims 47 and 48, Pinchuk fails to disclose an inner and outer tubular substrate as claimed. However, Lee teaches that it was known to use inner and outer tubular substrate with similar stents; see Figures 1, 2, 6, and 7 as well as column 4, line 41 to column 5, line 55. Therefore, it is the Examiner's position that it would have been obvious to use inner and outer tubular substrates on the Pinchuk stent for the

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same reasons as Lee and in order to provide a smoother surface along the blood flow path, thus preventing or reducing thrombosis.

With regard to claims 49 to 53, Pinchuk fails to disclose a wire member in planar ribbon form or a polymer cladding in quadrilateral cross-section as claimed. However, Lee teaches that it was known to form stents in planar or cylindrical form; see Figures 1 and 2 and compare with Figures 6 and 7. Hence it is the Examiner's position that it would have been obvious to form the wire of Pinchuk in a planar form in order to provide a lower profile, and thus, lower thrombogenic device than with a cylindrical wire member.

If a planar wire member was used in Pinchuk, the coating thereover would be in a quadrilateral configuration as claimed since it would coat a quadrilateral substrate. Similarly, the round wire would have a circular cross-section and the cladding thereover would also have a circular cross-section.

With regard to claim 56, if the cross-section were taken at crossover points (34,36) of Pinchuk, then the projection cross-section required by the claims would be present.

Allowable Subject Matter

Claims 54 and 55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed September 25, 2003 have been fully considered but they are not persuasive.

Upon review of the Applicant's argument that support for claims 47 and 48 is shown in Figures 2 and 3 as well as page 11, lines 4-17, the Examiner came to the conclusion that there is no clear support for the combination claimed. In other words, there is no support for the combination of overlapping polymer-clad layers encapsulated by inner and outer tubular substrates as claimed. Rather the inner and outer tubular substrates are placed over other embodiments of the disclosed invention. There is no indication that the tubular substrates can be placed over the overlapping polymer-clad embodiment.

In response to the arguments against the Pinchuk 35 USC 102(e) rejections, first, the Examiner asserts that Pinchuk discloses polymer cladding to the extent that this language can be given patentable weight.

Second, the steps of forming the device do not clearly impart structure to the final product that is distinct from that of Pinchuk. However, the rejection has been modified to account for the product-by-process limitation of the claim.

Third, the adjacent clad windings are at least overlapping along the axial axis such that this claim language is fully met. These overlapping regions are clearly joined by cladding material as shown in Figure 7.

With regard to the 35 USC 103 rejections, the Applicant has relied on the traversal of the Section 102 rejection. Therefore, the Section 103 rejections are

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considered valid because the arguments used against the Section 102 rejection was considered unpersuasive.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
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